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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,883	11/30/2000	Paul E. Harris	62682/JPW/PT	1468

7590 08/05/2004
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1185 Avenue of the Americas
New York, NY 10036

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,883

Applicant(s)

HARRIS ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8-11 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8-11 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 4/12/04 have been entered.

2. Claims 1-5, 8-11, and 13 are pending and under examination.

3. In view of Applicant's amendment and remarks, filed 4/12/04, all previous rejections have been withdrawn.

4. The following are new grounds for rejection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claims 1, 2, and 13, the recitation of "obtaining blood mononuclear cells through collection of monocytes and monocyte precursors" is nonsensical. Monocytes and monocyte precursors might be obtained from blood mononuclear cells but not vice versa as claimed.

B) In Claim 5, the cells of step (b) might be washed, but not the "tissue culture" as is recited in the claim.

C) In Claim 8, step (d) might be followed by step (e) (or the claim might recite "the method of Claim 1 further comprising (e) ... (f) ... (g) ...", but it is unclear how step (d) is to include steps (e-g) as is recited.

D) In Claims 1 and 2, "further processing the dendritic cell culture medium which remain in the container after step (c) and harvesting the processed dendritic cells" is both ungrammatical and nonsensical.

E) In Claim 13, it is unclear how "incubating said contents, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells" comprises a method of "preparing the

contents of the cell culture container... for culturing" as is recited in the claim.

F) In Claim 13, step (d), "incubating the contents of the cell culture container after the additional media are introduced into the cell culture container in step (c), in order to grow dendritic cell culture", is ungrammatical.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.

The instant invention is drawn to a method of "reproducibly generating dendritic cells (DCs)" comprising a method of cell culture. Note that the *in vitro* generation of dendritic cells was well known in the art at the time of the invention of the instant claims, however, performing the steps of the instant claims would not necessarily result in a product consisting of said cells given the breadth of the claims, i.e., the lack of specific limitations. As such, the method of the instant claims must be considered highly unpredictable and requiring of undue experimentation.

Step (d) comprises the actual culturing of adherent monocytes to produce DCs. As it is clear (see, for example, the title of the invention) that the method comprises a method of culturing human DC, the incubation of the adherent monocytes

would require the inclusion of specific reagents in the incubation, at minimum GM-CSF and IL-4 or IL-7 (see Schuler et al. as set forth in the Background of the Invention).

9. Claims 1-5, 8-11, and 13 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) "obtaining blood mononuclear cells through collection of monocytes and monocyte precursors separated substantially from lymphocytes ...[and culturing in media]... said media including at least rh-GM-CSF" (step a).

B) " further processing the dendritic cell culture medium which remain in the container after step (c) and harvesting the processed dendritic cells" (step d).

C) "harvesting the dendritic cell culture from the incubated contents of the cell culture container, including agitating said incubated contents, allowing the beads in the cell culture container to settle after said agitating, and expressing off cell culture suspension into another container," (step e).

D) In Claim 13, step (b), "preparing the contents of the cell culture container, including the medium and the blood mononuclear cells loaded into the cell culture container in step (a), for culturing, by incubating said contents, allowing beads with adherent cells attached thereto after incubation to settle, and then expressing off supernatant including nonadherent cells".

Applicant indicates that no new matter has been added but no support for these limitations can be found in the specification.

10. No claim is allowed.

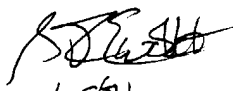
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

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12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.
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7/28/04
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